COVER STORY

Managing the Airwaves: New FCC Rules for Wireless Medical Telemetry

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> DONALD M. WITTERS, JR., CDRH/FDA

As a result of a new Federal Communications Commission (FCC) rule, expected to be released in early June, wireless medical telemetry will occupy a special place on the spectrum and will no longer have to accept electromagnetic interference, resulting in fewer potential hazards to patients. In addition, manufacturers are likely to realize a higher return on investment as they introduce improved medical telemetry products.

The new rules will be good news to Dallas' Baylor University Medical Center, which has been no stranger to electromagnetic interference (EMI). In 1998, experimental television signals strayed into the hospital's airspace and obliterated vital signs monitors for at least 12 heart-transplant and open-heart surgery patients milling around on the thirteenth floor. For two harrowing days, clinical engineers and broadcasting troubleshooters frantically tried to root out the source of the signal. Finally, a hospital clinical engineer traced the problem to WFAA-TV, a cross-town television station that was testing out its new digital TV signal.

In more and more hospitals, wireless medical telemetry is replacing bedside monitors because it enables patients to get on their feet and be mobile sooner, thus speeding their recovery. Also, this latest advance in hospital technology has become increasingly prevalent because it can be monitored from a central location, thus relieving the nursing staff of the need to make frequent room visits to inspect the monitor.

The Baylor incident touched off a highly dramatic conflict between the primary high-definition TV rights of the Dallas station and the secondary rights of the hospital. The collision of these technologies intensified an existing FCC review that is expected to result in a final rule at its June 8 meeting. According to FCC officials, it is expected to be very similar to the FCC's notice of proposed rulemaking (NPRM) issued last July.

Federal Agencies Had First Line of Action

Baylor hospital officials said the signal was unlike any they had seen before and took up the entire 6 MHz band. Soon after the origin was found, hospital officials worked quickly with the television station management to curb the interference.

Although no one was injured in the February 1998 incident, the consequences literally could have been a matter of life and death, said Steven Juett, Baylor's director of medical engineering. He is credited with tracking the interference to its source.

"Those patients were recovering from surgery and may have had arrhythmia for which the monitor might detect a life-threatening event," he said. "Without that

The definition of medical telemetry according to the AHA's Spectrum Selection Workgroup:

"Medical telemetry is defined as the wireless transfer of information associated with the measurement, control, and/or recording of physiological parameters and other patient-related information between points separated by a distance, usually within the healthcare facility."

equipment, the result could have been patient death. There would have been no intervention."

Although government and health officials had been quietly working to find a solution for several years, the extensive media attention focused on concerns about patient safety, thus catapulting wireless medical telemetry from a little known subject to a dynamic issue splashed on the nation's front pages and evening news programs. Those concerns were intensified after similar interference incidents occurred later in 1998 in Atlanta, Houston, and Philadelphia.

In reality, the FCC began reviewing the potential for interference into medical telemetry in 1997. In addition, the FDA's Center for Devices and Radiological Health (CDRH) has been in discussions with the FCC and manufacturers for a number of years about the problem, according to Donald M. Witters Jr., biomedical engineer with the Office of Science and Technology, CDRH, and member of the AAMI Electromagnetic Compatibility Work Group.

The FCC's initial response after the Baylor incident was to put into place immediate precautions on medical telemetry, said Hugh Van Tuyl, senior engineer in the Office of Engineering and Technology, FCC. For example, the FCC compiled a list of DTV (digital television) stations on its Web site (www.fcc.gov/oet/faqs/medical.html) so hospitals could find out whether any television stations were going to be testing digital signals near them. Furthermore, the FCC asked any TV stations moving to DTV transmission to contact hospitals in their area before going on the air to determine if any conflict would result, he said.

Similarly, the FDA leapt into action by circulating an alert that communicated the potential for interference from digital television in a letter to manufacturers, he said. "The FDA coordinated with the FCC to understand and deal with the problem very quickly," Witters said.

Witters noted that Dr. Elizabeth Jacobson, CDRH Deputy Director for Science, joined by the FCC, asked the American Hospital Association (AHA) to form a national task force to study the issue. "Because of concerns for the patients we serve, we jumped at the chance to organize this group," added Mary Beth Savary Taylor, AHA director, executive branch relations.

The AHA Medical Telemetry Task Force's charter was to recommend to the FCC appropriate bandwidth and utilization requirements for medical telemetry and provide the FCC with enough information for the agency to authorize a protected medical telemetry frequency band, within which medical telemetry would be a primary licensee.

The task force's first meeting was in September 1998. In April 1999, the task force submitted to the FCC its final report recommending dedicated spectrum for medical telemetry equipment. Another major part of the AHA task force's research was to conduct a nationwide survey to determine the current and future needs for medical telemetry devices. The research effort included primary telemetry vendors such as VitalCom, Agilent Technologies, Spacelabs Medical, and GE Marquette, plus several hospitals and healthcare delivery systems and professional organizations.

New Rules Will Require Time for Implementation

"Once the FCC proposal becomes a final rule, the AHA Medical Telemetry Task Force members agree that the opportunity for drastically reducing interference to wireless medical telemetry is at hand," Witters summarizes.

Health officials say they hope the dedicated bandwidth will leave medical telemetry free from interference from digital television or land mobile communication. Among its principal features are to bolster patient safety as well as to allow for other diverse uses of wireless transmissions, including two-way communication.

But Witters cautions it will take time to implement and coordinate the new service. He explained that the FDA is taking this into account and has been developing plans to work with device manufacturers to get their new devices to market as quickly as possible.

Not all health groups were in agreement on how the spectrum should be used. Some groups unsuccessfully lobbied the FCC to include voice and video transmissions in the final rule bandwidth. The FCC rejected these requests because they were thought to use too much of

Timeline

1993	Critical Care Telemetry Group forms to discuss patient care and wireless medical telemetry
1998	Spectrum interference incident occurs at Baylor University Medical Center
1998	American Hospital Association forms Task Force on Medical Telemetry
1999	FCC issues notice of proposed rule
June 2000	FCC final rule anticipated
2003	All TV broadcasters will move to digital transmission, increasing the amount of available bandwidth

the spectrum, says Van Tuyl. He drafted last July's notice of proposed rulemaking and is developing the final orders.

FCC staff members are tight-lipped about the phrasing of the final rule until it has cleared the commission. But they expect it to include one of two options that have been under consideration. The first would include three bands: 608–614 MHz, 1395–1400 MHz and 1429–1432 MHz. The second would include two bands: 608–614 MHz and 1391–1400 MHz, Van Tuyl says.

These frequencies are the most likely to be dedicated to medical telemetry because they are now available or were reallocated to non-governmental use, he said. For example, 1390–1400 MHz and 1427–1432 MHz have already been reallocated to non-governmental purposes. He says 608–614 MHz is TV channel 37 and has been used largely for radio-astronomy. In 1997, the FCC began allowing medical telemetry transmissions on this channel, he said.

Apart from freeing up more space for medical telemetry during a reallocation of the spectrum, the rule likely will buffer the hospital wireless telemetry from interference from land mobile communications, such as police and fire personnel, Van Tuyl said.

Medical telemetry and land communications units currently use the same 450–470 MHz frequency. Land mobile communications is the primary user, with medical telemetry in a secondary role. In 1995, the commission reduced the channel space. "The problem was that it put land users on top of medical telemetry," Van Tuyl observes. Consequently, the FCC put a freeze on new land mobile applications and will work to protect medical telemetry from any future interference in its primary status in new frequency bands.

What to Do Before the Ruling Takes Effect

The Baylor incident identified several vital issues for hospital officials, manufacturers, and regulators: It highlighted the healthcare industry's susceptibility to interference from the onset of digital television; it raised profound concerns about patient safety; and it provoked a litany of questions about how hospitals and manufacturers can best prepare themselves for future product innovation and for important changes in day-to-day equipment management operations.

While waiting for the ruling to be implemented, all healthcare institutions should factor the forthcoming FCC changes into their routine technology assessments, recommends Caroline Campbell, director of biomedical engineering at the Washington Hospital Center (Washington, DC). She was among six participants in a March 2000 telephone call to prepare for the ACCE Symposium scheduled for June 3 at the AAMI 2000 conference in San Jose, Calif.

Other participants in the discussion included Van Tuyl; Witters; Brian Porras, technology assessment specialist at Premier Inc.; Savary Taylor; and Stan Wiley, director, product development, Telemetry Products for Spacelabs Medical (Redmond, WA).

"As hospitals make their capital equipment plans, they certainly need to be aware of the FCC ruling and the proposed timelines," Campbell said. "Wireless communications are here to stay. In fact, hospitals are taking advantage of the efficiencies offered by wireless communications devices by incorporating them into their patient care processes."

"Given the competition for capital budgets, it is important to be looking to the future," said Porras. "Capital budget dollars may not be approved for two or three years." He will moderate the ACCE Symposium at the AAMI 2000 Annual Conference and Expo in June.

Hospital profit margins are dropping precipitously and the competition for available funds will become more intense in future months, noted Savary Taylor. She cited a recent MEDPAC study that found that hospital profits in 1998 sank to their lowest level in 20 years.

She said a survey of 14 hospitals of various sizes conducted for the Physiologic Parameters Workgroup, a subdivision of the AHA Task Force, found that telemetry is not being used enough because of concerns about its reliability. If interference were not of concern, medical telemetry would be used more extensively and in new

Highlights of the FCC July 1999 Proposal

Last July, the FCC issued a proposed rulemaking that would allow potentially life-critical medical telemetry equipment to operate on a blanket-licensed, interference-protected basis. The final FCC rule, due to be addressed at the June 8 meeting, is expected to be very similar to an earlier proposal.

Currently, medical telemetry equipment operates on a secondary basis and is unprotected from interference from primary users. But in its proposal, the FCC tentatively concluded that it was necessary to find additional spectrum for medical telemetry equipment and that the spectrum should be allocated on a primary basis to protect against interference.

The FCC invited comments on two alternative allocation proposals: 608–614 MHz, 1395–1400 MHz and 1429–1432 MHz or 2) 608–614 MHz and 1391–1400 MHz.

places such as labor and delivery suites where expectant mothers may need to walk about to promote labor but still need to be monitored, Campbell says.

"The work group learned that the spectrum needs are increasing rapidly based on a growing elderly population with its cadre of health issues and a rising of acuity of patients," Campbell said. "This means that patients who were formally housed in the ICU are now housed on the general nursing units where they still require the monitoring and treatment capabilities" that could be delivered only in the ICU setting.

Campbell encouraged clinical engineers to assess how quickly their institutions need to migrate to new frequencies based on three factors: the FCC's time projections, the risks presented by current usage, and where the current technology is in its life cycle. In short, healthcare institutions should determine which frequency bandwidth they currently are using, what the risks are, and how quickly they need to migrate based on the FCC's expected timeframes, she said.

Additional Challenges Lie Ahead

For example, if a healthcare institution is using a band that has been allocated to a new DTV station, it should notify the station at once and plan on moving out of the band prior to the beginning of the digital broadcasts "in order to be out of harm's way," she said.

Institutions operating within the VHF band are not in the clear either, Campbell said. Those sites may not be allocated to DTV, according to the FCC's Web site, but healthcare institutions should be concerned about low-powered TV broadcasts that might lead to signals being crossed at some point in the future, she said.

Low-powered TV broadcasts include public television stations that obtain broadcast licenses for a narrowly defined area at a reduced cost. But with the onset of digital television, some low-powered TV stations could be bumped from their current operating frequency and want to migrate to frequencies being used today by medical telemetry, Campbell warned.

She also advised a healthcare institution operating in the 450–470 MHz band to watch information from the FCC very closely so that they would quickly learn when the freeze on the land mobile band will be lifted.The AHA Task Force on Medical Telemetry has urged the FCC not to precipitously lift this freeze.

"Through the [proposed rule last July] hospitals are becoming aware that changes are in the works with respect to technical requirements for new equipment," said Wiley.

The pending ruling also will have important consequences for manufacturing and will likely lead to the development of new equipment and new applications, Van Tuyl concluded.

Of course, there are also many challenges ahead. For example, Wiley explained that signal migration requires becoming more familiar with the transmission characteristics that may be unique in each hospital setting.

The number of patients to be monitored may also

Parameter Use Models

The Clinical Parameters Workgroup developed a model for monitored parameter usage and duration by conducting a survey. The survey was administered to geographically dispersed hospital administrators, biomedical engineering directors, principal clinicians responsible for medical telemetry, and clinical professional organizations. A summary of the survey results is as follows:

Telemetry Monitoring Needs Model

Physiologic Parameter	Concurrent Patients	Concurrent Use Model	Number of Concurrent Waveforms	Required Bandwidth
Adult electrocardiagram	200–600	500	3	4.000 MHz
Pulse oximetry	16–210	250	1	0.150 MHz
Obstetrical (fetal/maternal) parameters	0–150	100	3	1.300 MHz
Invasive pressures	17–420	300	2	0.400 MHz
Respirations	4–210	100	1	0.025 MHz
12 sets of parametric data	up to 500 patients	500	0	0.0250 MHz

Source: Clinical Parameters Workgroup

This amount of spectrum is expected to double if one considers a growth in five to ten years to 1000 telemetry transmitters.

Recommended Actions for Hospitals in Light of FCC Rule

1. Hospitals should be aware of the forthcoming (June 8) FCC rule and its timelines.
2. Clinical engineers should assess how quickly their institutions need to migrate to new frequencies based on the FCC's time projections, the risks presented by current usage, and status of current technology.
3. Hospitals operating within the VHF band should be aware that they are not completely in the clear of interference. While those frequencies may not yet be allocated to digital television, hospitals should be concerned about low-powered TV broadcasts that might lead to signals being crossed at some point in the future.

prove challenging. The AHA survey was oriented toward asking the healthcare industry which physiological parameters they would monitor and how many patients they would monitor optimally if they could use wireless technology.

The results of the survey indicated that—regardless of size or geographic location—hospitals predicted they would monitor up to 1,000 patients during the next 10 years and would plan on monitoring all physiological parameters from patients, said David Pettijohn, a task force member and vice president of strategic accounts and technology at Vital Com. He is the author of a new paper, "HDTV, Land Mobile Communications and the New FCC Rules, An Historic Opportunity," which will be presented during the upcoming AAMI 2000 Annual Conference & Expo.

"The surprising thing is that the survey results came back pretty much the same regardless of a hospital's size or geographic location," he said. From the baseline of industry requirements, conservative computations indicated that accommodation of these capabilities would require 12 MHz bandwidth, Pettijohn said.

The Task Force also obtained FCC agreement for its recommended rules for operation of medical telemetry as a primary licensee. These include the definition of medical telemetry as "the transmission of physiological data from any device directly connected to a patient." This includes waveforms and alphanumeric physiological data, demographics, and control functions.

The FCC has indicated that it will permit the use of any communications technology so long as it conforms to the current rulemaking. Finally, the 6 MHz band is partitioned into four segments in order that both wideband and narrowband technologies may coexist within a single facility.

"The whole point is to give us a protected band. Other people will be prohibited from interfering with us," Pettijohn said. "It will be a clean band and therefore we will not have to worry about digital television or land mobile communications. And it does offer us vendors the opportunity to come out with technologies as good as a wire."

But the new bands won't leave the airwave risk-free, Pettijohn added. "The problems that have plagued medical telemetry in the past are going to go away for the most part, although we will still have noise from other instrumentation in the hospital," he said.

However, hospital staff are hopeful that they will be able to take a positive approach. "The lessons learned in the telemetry arena will prompt hospitals to more proactively manage their spectrum, thereby reducing even this potential for interference from hospital instrumentation," Campbell said.